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TELEFAX

Date: July 6, 2004 **Total pages:** 19

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Our Docket No. ICI 102
Your Docket No. **Client/Matter No.** 078230/00027

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MESSAGE:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stefan Dietmar Anker and Andres Justin Stewart Coats

Serial No.: 09/807,558 Art Unit: 1647

Filed: July 17, 2001 Examiner: Fozia M. Hamud

For: *METHODS OF TREATMENT*

PTO/SB/21 (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/807,558
Filing Date	July 17, 2001
First Named Inventor	Stefan Dietmar
Art Unit	1647
Examiner Name	Fozia M. Hamud
Attorney Docket Number	ICI 102

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- ☑ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment/Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☑ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Patrea L. Pabst, Esq., Reg. No. 31,284 Pabst Patent Group LLP 400 Colony Square, Suite 1200; 1201 Peachtree Street, N.E.; Atlanta, GA 30361
Signature	
Date	July 6, 2004

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Typed or printed name	Brian K. Adams		
Signature		Date	July 6, 2004

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PTO/SB/17 (10-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 130.00

Complete if Known	
Application Number	09/807,558
Filing Date	July 17, 2001
First Named Inventor	Stefan Dietmar
Examiner Name	Fozia M. Hamud
Art Unit	1647
Attorney Docket No.	ICI 102

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: **50-3129**

Deposit Account Name: **Pabst Patent Group LLP**

The Director is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) or any underpayment of fee(s)

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below	Fee Paid
Total Claims	40 -40* =		X	=
Independent Claims	9 -9** =		X	=
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	130
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) 130

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Patrea L. Pabst	*Registration No. (Attorney/Agent)*	31,264	*Telephone*	(404) 879-2151
Signature				*Date*	July 6, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stefan Dietmar Anker and Andres Justin Stewart Coats

Serial No.: 09/807,558 Art Unit: 1647

Filed: July 17, 2001 Examiner: Fozia M. Hamud

For: *METHODS OF TREATMENT*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

Sir:

Pursuant to Pursuant to 37 C.F.R. § 1.144, applicants petition the Group Director to review the restriction requirement set forth in the Office Action mailed on January 6, 2004, as maintained in the Office Action mailed on May 3, 2004. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

Remarks

In the Office Action mailed January 6, 2004, the claims were divided into 16 groups. The claims, as pending, are attached as an Appendix for the convenience of the Group Director.

Claim 1 is directed to a method of treating weight loss due to underlying disease in a patient the method comprising administering to the patient an effective amount of an agent which reduces sympathetic nervous system activity.

Group I Claims 1-3, 19, 29-31, 35-36, 38-39, (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone.

Group II Claims 1-2, 5, 6, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 6, drawn to a method of administering to a patient a chymase inhibitor.

Group III Claims 1-2, 7, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 8, drawn to a method of administering to a patient a cathepsin inhibitor.

Group IV Claims 1-2, 9, 11, 13, 15, 19, 23, 29-31, 35-36, 38-39, 41 (in part) and claims 10, 12, 16 and 24, drawn to a method of administering to a patient a receptor blocker.

Group V Claims 1-2, 17, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 18, drawn to a method of administering to a patient a ganglion blocking agent.

Group VI Claims 1-2, 19, 21, 29-31, 35-36, 38-39, 41 (in part) and claim 20, drawn to a method of administering to a patient an opiate.

Group VII Claims 1-2, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 22, drawn to a method of administering to a patient a compound that inhibits the effect of scopolamine.

Group VIII Claims 1-2, 19, 25, 29-31, 35-36, 38-39, 41 (in part) and claim 26, drawn to a method of administering to a patient a xanthine oxidase inhibitor.

Group IX Claims 1-2, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 27, drawn to a method of administering to a patient an erythropoietin.

Group X Claims 1, 19, 29-31, 35-36, 41 (in part) and claim 14, drawn to a method of administering to a patient a receptor agonist.

Group XI Claims 38 and 39 (in part), drawn to a method of administering to a patient a digitalis alkaloid.

Group XII Claims 38 and 39 (in part), drawn to a method of administering to a patient a growth hormone.

Group XIII Claims 38 and 39 (in part), drawn to a method of administering to a patient an insulin like growth factor.

Group XIV Claims 38 and 39 (in part), drawn to a method of administering to a patient an endothelin antagonist.

Group XV Claims 38 and 39 (in part), drawn to a method of administering to a patient a TNF antagonist.

Group XVI Claims 28, 37, 40 and 46-47, drawn to a method of electrically stimulating a patient's muscles.

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

Applicants provisionally elected Group I, Claims 1-3, 19, 29-31, 35-36, 38-39, (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone with traverse.

The Restriction Requirement is Improper.

The Examiner has applied PCT rules for Unity of Invention because this application is a 371 of PCT/GB99/03302. PCT Rule 13.2 deals with the requirement of unity of invention and defines the method for determining whether the requirement is satisfied. "Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features".

The independent claims in the present application are sufficiently linked as to form a single general inventive concept defined by claim 1. This inventive concept finds expression in common technical features which define the inventive contribution that the claims invention makes over the prior art- specifically to treat weight loss by administering an inhibitor of sympathetic nervous system activity. The Examiner has improperly limited the scope of the claimed invention to a single species defined as one of several compounds, listed in dependent claim 2. Even as to this single species, the reference cited by the Examiner, Mueller and Ayres, J. Clin. Invest. 65: 338-346 (1980), does not teach or suggest the use of propanolol for the treatment of cachexia, nor has the examiner provided a basis in fact and/or technical reasoning to reasonably support the determination that this allegedly inherent characteristic of propanolol

necessarily flows from the teachings of Mueller and Ayres. *In Ex parte* Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int'f., 1990).

At most, the claims should have been divided into the following groups along with an election of species for the compound to reduce sympathetic nervous system activity.

Group I: claims 1-27, 29-31, 35 and 36 drawn to a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity.

Group II: claims 28, 37, 46 and 47 drawn to a method of treating weight loss by electrically stimulating the patient's muscles.

Group III: claims 38-40 drawn to a method of enhancing exercise performance.

Group IV: claim 41 drawn to a method of treating weight loss associated with a cardiovascular disorder.

The Claims meet the Unity of Invention Standards for Markush Practice

PCT Rule 13.2 also governs so called Markush practice. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present,

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the present application, the claims have the common property/ activity of decreasing sympathetic nervous system activity and are all recognized as being sympathetic nervous system blockers. These are known compounds with recognized activities and classification, although not for treating weight loss.

Division of Single Claims into Multiple Inventions is Improper

It is improper to divide a single claim such as claim 1 into a plurality of inventions as the Examiner has done. Proper practice would be to require an election of species for search purposes. It is understood that once a species is determined to be free of prior art, the remaining species will also be searched.

The proper restriction in the instant application would be to divide the claims based on the method of treatment as described above and require an election of species for the compound to be administered.

Claims 1-27, 29-31, 35 and 36 all clearly define essential characteristics of the single embodiment of the invention that being *a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity.* The examiner has divided the generic claims into different groups based on description in the specification of what molecules can be used, *even in the complete absence of any such limitations in the claims!*

There is **no limitation** in the independent claim to specific compounds to inhibit sympathetic nervous system activity. Clearly, the examiner is trying to impose limitations not present in the claims through the vehicle of a restriction requirement, without examination under 35 U.S.C. § 102, 103 or 112.

It is stated in the MPEP that, "where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are but different definitions of the same disclosed subject matter, varying in breadth or scope of definition." (MPEP 806.03)

The case has already been pending for three years. In that time the Examiner has issued two restriction requirements and a letter requesting clarification- prosecution has been delayed.

The restriction requirement, by creating separate inventions out of the generic claims, makes it impossible to examine the claims in their entirety, and forces the applicants to restrict it to a single species. The examiner has no legal authority to require applicants to restrict a generic claim to a single species, absent prior art or lack of enablement.

Summary

The current restriction imposed on the claims of the present invention is improper. This restriction is inconsistent with the guidelines for restriction practice delineated by the MPEP and PCT rules. Upholding this restriction requirement would be to allow the examiner to impose limitations on the claims ***which are not now present.***

U.S.S.N. 09/807,558
Filed: July 17, 2001
PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

Favorable consideration of this petition is earnestly solicited.

Respectfully submitted,

Patrea L. Pabst
Reg. No. 31,284

Date: July 6, 2004

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Atlanta, Georgia 30361
(404) 879-2151
(404) 879-2160 (Facsimile)

Certificate of Facsimile Transmission

I hereby certify that this Petition for Reconsideration of Restriction Requirement, and any documents referred to as attached therein are being facsimile transmitted on the date shown below, to the Commissioner for Patents, U.S. Patent and Trademark Office, Alexandria, VA 22313-1450.

Brian Adams

Date: July 6, 2004